Docket No.: 48850-036 PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Application of	:	
Christian MAYAUD	:	
Serial No.: 09/201,107	:	Group Art Unit: 2165
Filed: November 30, 1998	:	Examiner: M. Kemper
For: PRESCRIPTION MANAGEMENT SYSTEM	:	

APPEAL BRIEF

Commissioner for Patents
Washington, DC 20231

Sir:

This is an appeal from the final rejection of the Examiner dated November 7, 2000. A notice of appeal was filed on April 9, 2001.

I. REAL PARTY IN INTEREST

The real part in interest is ANDRX CORPORATION.

II. RELATED APPEALS AND INTERFERENCES

The Applicant is unaware of any related appeals or interferences that would affect a decision in this appeal or that would be affected by a decision in this appeal.

III. STATUS OF CLAIMS

Claims 70-85 are pending in this application. Claims 70, 76, 77, and 79-84 have been rejected.

Claim 71-75, 78, and 85 have not been rejected by the Examiner in the final Office Action. Accordingly, claims 71-75, 78, and 85 have been indicated as allowable, subject to an objection based on being dependent upon a rejected claim.

IV. STATUS OF AMENDMENTS

No amendments have been filed subsequent to the Final Office Action

V. SUMMARY OF INVENTION

The invention relates generally to automated prescription writing. Several embodiments are reflected in the claims. Some embodiments of the present invention relate to a system being operative to display an electronically generated prescription history of a patient's prior prescribed treatments (e.g. Claim 79). Such embodiments provide a prescriber drug list of individual drug selections or suggestions based upon historical prescription activity (Page 13, lines 9-17 of the specification). Displayed prior prescription information can include, for a selected prescription, the condition for which a drug is prescribed, the drug name, date of prescription, dates of any renewals, and identification information of a prescribing physician (Page 114, lines 10-20 of the specification and Figure 12).

Other embodiments of the present invention provide for multiple record-independent facilities (e.g. Claim 79). These embodiments enable user interface devices to establish contact with a host computer facility, requiring only that the user interface devices have operating systems that are communications-equipped (Page 128, lines 20-24 of the specification and Figure 15).

Other embodiments of the present invention provide for access control that is maintained by reference to record-access specifications provided in a security profile provided in a pre-authorization

file (e.g. Claim 84). These embodiments provide access control specifications detailing permissible levels of third-party access to prescription related data. User preferences may include authorization for data access by various third parties (Page 50, line 20 through page 51, line 5 of the specification).

Other embodiments of the present invention provide for drug formulary information identifying at least one of multiple drugs as a patient's drug formulary preferences to enable selection by the prescriber of a benefit plan recommended drug (e.g. Claim 70). These embodiments provide a system for a prescription benefits management company that reduces overall prescription costs by using volume purchasing to get preferred pricing on selected drugs (Page 98, line 22 through Page 99, line 10 of the specification).

Other embodiments of the present relate to a prescription creation system comprising a drug contraindication review routine accessing contraindication information regarding a prescribed drug and an alert regarding relevant contraindications (e.g. Claim 76). These embodiments provide a prescription management system with the ability to review a completed prescription for contraindications, such as patient allergies to prescribed drugs and possible drug-to-drug interactions with other drugs a patient has been previously prescribed (Page 85, lines 11-17 of the specification).

VI. ISSUES

A. Whether the Examiner failed to established a *prima facie* case of anticipation in the rejection of claims 79-83 under 35 U.S.C. 102(e) as being clearly anticipated by Goldman et al. (U.S. Patent No. 5,542,420).

B. Whether the Examiner failed to established a *prima facie* case of anticipation in the

rejection of claim 84 under 35 U.S.C. 102(a) as being clearly anticipated by Faden et al. ("Privacy and Security of Personal Information in a New Health Care System", JAMA 11/93).

C. Whether the Examiner failed to established a *prima facie* case of obviousness in the rejection of claim 84 under 35 U.S.C. 103(a) as being unpatentable over Ballantyne et al. (U.S. Patent No. 5,867,821) in view of Faden et al. ("Privacy and Security of Personal Information in a New Health Care System", JAMA 11/93).

D. Whether the Examiner failed to established a *prima facie* case of obviousness in the rejection of claim 70 under 35 U.S.C. 103(a) as being unpatentable over Fox ("RxWriter", Journal of Family Practice, v.37, n.3, p. 296, 9/1993).

E. Whether the Examiner failed to established a *prima facie* case of obviousness in the rejection of claims 76-77 under 35 U.S.C. 103(a) as being unpatentable over Fox ("RxWriter", Journal of Family Practice, v.37, n.3, p. 296, 9/1993).

VII. GROUPING OF CLAIMS

Each claim is argued separately and no claim stands or falls with any other claims.

VIII. THE ARGUMENT

A. The Examiner has failed to established a *prima facie* case of anticipation in the rejection of claims 79-83 under 35 U.S.C. 102(e) as being clearly anticipated by Goldman et al.

(U.S. Patent No. 5,542,420).

Claim 79 requires a "...system being operative to display an electronically generated prescription history of a patient's prior prescribed treatments at multiple record-independent facilities..."

To establish a *prima facie* case of anticipation under 35 U.S.C. § 102, a single prior art reference must describe each and every element as set forth in the subject claim. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). "The identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). Also see M.P.E.P. § 2131.

Goldman et al. is directed to a personalized method and system for storage, communication, analysis, and process of health related data. Specifically, Goldman et al. is directed to a health care system for specifying edibles to individual subjects, i.e., for weight loss. In column 17, lines 15-32, Goldman et al. disclose a pharmacy terminal which displays an individual's prescription.

Goldman et al. does not disclose a system being operative to display an electronically generated prescription history of a patient's prior prescribed treatments at multiple record-independent facilities, as required by claim 79. This is apparent as the "system" of Goldman et al. consists of a single database 26. This is supported in Figures 2-3 and the accompanying description in column 7, lines 54-60 which discloses that "[t]he database 26 (center) constitutes a substantial storage capacity...with basic historical data on a multitude of individuals subjects." A system consisting of a single database is repugnant to the claimed "record-independent facilities". Accordingly, Goldman et al. does not clearly anticipate claim 79 under 35 U.S.C. § 102(e), as the claim element of "multiple record-independent facilities" is not disclosed in Goldman et al.

Dependant claim 80 is allowable for the same reasons stated above for independent claim 79.

Further claim 80 requires "...a patient condition list for selection of a patient condition for posting to the prescription, the patient condition list comprising patient conditions listed in the patient history record...", which is not disclosed in Goldman et al.

Dependant claim 81 is allowable for the same reasons stated above for independent claim 79. Further claim 81 requires "...a source-oriented data-retrieval subsystem, the data retrieval subsystem being connected to access at least one data-retrieval network to retrieve source prescribing information and patient-related data to the point-of-care from at least one remote source database..." , which is not disclosed in Goldman et al.

Dependant claims 82 and 83 are allowable for the same reasons stated above for independent claim 79. Further claim 82 and 83 require that "...the patient history record is a contemporaneous record dynamically assembled from multiple source record elements retrieved from multiple heterogenous remote databases...", which is not disclosed in Goldman et al.

B. The Examiner has failed to established a *prima facie* case of anticipation in the rejection of claim 84 under 35 U.S.C. 102(a) as being clearly anticipated by Faden et al. ("Privacy and Security of Personal Information in a New Health Care System", JAMA 11/93).

Claim 84 relates to a patient data access control software system and requires that "...access control is maintained by reference to record-access specifications provided in a security profile in a pre-authorization file..."

As discussed above, to establish a *prima facie* case of anticipation under 35 U.S.C. § 102, a single prior art reference must describe each and every element as set forth in the subject claim. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir.

1987). "The identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). Also see M.P.E.P. § 2131.

Faden et al. relates to the examination of privacy and security goals for the collection, storage, and use of health care information in a new health care system and means to attain those goals. It is disclosed on page 8, that "[d]ata protection policies...must not be tied to specific systems and system capabilities but, rather, must establish security protection guidelines that define system goals but do not specify how these goals will be reached...[these goals] should guarantee that only authorized persons are able to access record for authorized purposes at authorized times." Faden et al. does not disclose "...access control is maintained by reference to record-access specifications provided in a security profile in a pre-authorization file...", as required by claim 84. This is apparent, as Faden et al. merely relates to policies of health care systems and not the specifics of how "access control is maintained". Accordingly, Faden et al. does not clearly anticipate claim 84 under 35 U.S.C. § 102(e), as the claim element of "...access control [that] is maintained by reference to record-access specifications provided in a security profile in a pre-authorization file..." is not disclosed in Faden et al.

C. The Examiner has failed to established a *prima facie* case of obviousness in the rejection of claim 84 under 35 U.S.C. 103(a) as being unpatentable over Ballantyne et al. (U.S. Patent No. 5,867,821) in view of Faden et al. ("Privacy and Security of Personal Information in a New Health Care System", JAMA 11/93).

As discussed above, claim 84 relates to a patient data access control software system and requires that "...access control is maintained by reference to record-access specifications provided in a security profile in a pre-authorization file..."

To establish a *prima facie* case of obviousness under 35 U.S.C. § 103, three basic criteria must be met. First, the prior art reference (or references when combined) must teach or suggest all the claim limitations. Second, there must be some suggestion or motivation in the references themselves to modify the reference or to combine reference teachings. Third, there must be a reasonable expectation of success for the modification or combination of references. Further, the teaching or suggestion to make the modification or combination of prior art and the reasonable expectation of success must both be found in the prior art, and not based on Applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). Additionally, there must be particular finding as to the specific understanding or principle within the knowledge of a skilled artisan that would have motivated one with no knowledge to the claimed invention to combine or modify references. *In re Kotzab*, 217 F.3d 1365, 55 U.S.P.Q.2d 1313 (Fed. Cir. 2000). Also see M.P.E.P. § 2143.

Ballantyne et al. relates to a method and apparatus for electronically accessing and distributing personal health care information and services in hospitals and homes. In column 8 of Ballantyne et al., a security process is disclosed, wherein "...each user first enters their ID number...[t]his ID number is then validated...with a central user list to confirm they are a legitimate user." The disclosure of Ballantyne et al., is unlike the requirements of claim 84, as a central user list does not teach or suggest the claimed "pre-authorization file". This is apparent, as the claimed "pre-authorization file" is specific to "record-access specifications providing in a security profile", while a central user list is merely a list of legitimate users, wherein any of the legitimate users can access any record on the system. Accordingly, Ballantyne et al. does not teach or suggest the claimed "pre-authorization file", as required by claim 84.

As discussed above, Faden et al. relates to the examination of privacy and security goals for the collection, storage, and use of health care information in a new health care system and means to attain

those goals. It is disclosed on page 8, that "[d]ata protection policies...must not be tied to specific systems and system capabilities but, rather, must establish security protection guidelines that define system goals but do not specify how these goals will be reached...[these goals] should guarantee that only authorized persons are able to access record for authorized purposes at authorized times." Faden et al. does not disclose "...access control is maintained by reference to record-access specifications provided in a security profile in a pre-authorization file...", as required by claim 84. This is apparent, as Faden et al. merely relates to policies of health care systems and not the pertinent specifics of how "access control is maintained". Accordingly, Faden et al. does not alleviate the deficiency of Ballantyne et al. not teaching or suggesting the claimed "pre-authorization file", as required by claim 84.

The Examiner has not established a *prima facie* case of obviousness in the rejection of claim 84 under 35 U.S.C. § 103(a) for several reasons. First, neither Ballantyne et al. nor Faden et al., alone or in combination, teach or suggest "a pre-authorization file", as required by claim 84. Second, both Ballantyne et al. and Faden et al. each lack the requisite particular motivation to be combined with the other. This is apparent, as Faden et al. does not relate to security protocol specifics and Ballantyne et al. merely relates to a central user list. Third, there is a lack of the requisite reasonable expectation of success for the combination, at least because all of the claim elements are not taught by the cited prior art and there is a lack of particular motivation for the combination of the cited prior art. At least for these reasons, the Examiner has not established a *prima facie* case of obviousness.

D. The Examiner has failed to established a *prima facie* case of obviousness in the rejection of claim 70 under 35 U.S.C. 103(a) as being unpatentable over Fox ("RxWriter", Journal of Family Practice, v.37, n.3, p. 296, 9/1993).

Claim 70 requires a "...prescription creation system providing...drug formulary information

identifying at least one of multiple drugs as a patient's drug formulary preferences to enable selection by the prescriber of a benefit plan recommended drug..."

As discussed above, to establish a *prima facie* case of obviousness under 35 U.S.C. § 103, three basic criteria must be met. First, the prior art reference (or references when combined) must teach or suggest all the claim limitations. Second, there must be some suggestion or motivation in the references themselves to modify the reference or to combine reference teachings. Third, there must be a reasonable expectation of success for the modification or combination of references. Further, the teaching or suggestion to make the modification or combination of prior art and the reasonable expectation of success must both be found in the prior art, and not based on Applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). Additionally, there must be particular finding as to the specific understanding or principle within the knowledge of a skilled artisan that would have motivated one with no knowledge to the claimed invention to combine or modify references. *In re Kotzab*, 217 F.3d 1365, 55 U.S.P.Q.2d 1313 (Fed. Cir. 2000). Also see M.P.E.P. § 2143.

Fox relates to a critique of the prescription writing software product "Rxwriter". Fox contains no disclosure of "drug formulary information identifying at least one of multiple drugs as a patient's drug formulary preferences." The Examiner asserts that "Fox also describes...drug formulary information (generic drugs)..." However, this assertion is substantively flawed, as Fox merely discloses that "[t]here is no distinction or cross-referencing between generic and brand names." This disclosure clearly does not teach or suggest "identifying at least one of multiple drugs as a patient's drug formulary preferences", as required by claim 70.

The Examiner asserts that "...it would have been obvious to one having ordinary skill in the art at the time of the invention to have implemented the ... drug formulary information since this

information would have improved the efficiency and thoroughness of the system suggested by Fox." Formulary preferences have nothing to do with "efficiency and throughness. This the Examiner's rationale for the combination is defective.

The Examiner has not established a *prima facie* case of obviousness in the rejection of claim 70 for several reasons. First, the prior art reference of Fox does not teach or suggest all of the limitations required by claim 70. This is apparent, as Fox contains no disclosure of "...drug formulary information identifying at least one of multiple drugs as a patient's drug formulary preferences to enable selection by the prescriber of a benefit plan recommended drug..." Second, the prior art reference of Fox lacks the requisite particular motivation to be modified to teach the claimed present invention, as Fox does not relate to "drug formulary information". Third, the requisite reasonable expectation of success for the modification of Fox is not satisfied, at least because Fox does not teach or suggest all of the claim limitation and Fox lacks motivation to be modified. Accordingly, the Examiner has not established a *prima facie* case of obviousness.

E. The Examiner has failed to established a *prima facie* case of obviousness in the rejection of claims 76-77 under 35 U.S.C. 103(a) as being unpatentable over Fox ("RxWriter", Journal of Family Practice, v.37, n.3, p. 296, 9/1993).

Claim 76 requires a "...prescription creation system...comprising a drug contraindication review routine...accessing contraindication information regarding the prescribed drug and an alert regarding a relevant such contraindication."

As discussed above, to establish a *prima facie* case of obviousness under 35 U.S.C. § 103, three basic criteria must be met. First, the prior art reference (or references when combined) must teach or suggest all the claim limitations. Second, there must be some suggestion or motivation in the

references themselves to modify the reference or to combine reference teachings. Third, there must be a reasonable expectation of success for the modification or combination of references. Further, the teaching or suggestion to make the modification or combination of prior art and the reasonable expectation of success must both be found in the prior art, and not based on Applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). Additionally, there must be particular finding as to the specific understanding or principle within the knowledge of a skilled artisan that would have motivated one with no knowledge to the claimed invention to combine or modify references. *In re Kotzab*, 217 F.3d 1365, 55 U.S.P.Q.2d 1313 (Fed. Cir. 2000). Also see M.P.E.P. § 2143.

As discussed above, Fox relates to a critique of the prescription writing software product "Rxwriter". Fox contains no teaching or suggestion of "...prescription creation system...comprising a drug contraindication review routine...accessing contraindication information regarding the prescribed drug and an alert regarding a relevant such contraindication." Further, the Examiner has not contended that Fox teaches this claim element required by claim 76.

The Examiner has not established a prima facie case of obviousness at least because the cited prior art reference of Fox does not teach or suggest all of the claim elements required by claim 76. Further, Fox does not contain any particular motivation or suggestion to modify Fox to teach this limitation.

Dependant claim 77 is allowable for the same reasons stated above for independent claim 76. Further claim 77 requires "...the prescription management system retrieves patient drug history, or patient allergy data specific to the patient at the point-of-care and is linked to a data-retrieval subsystem to obtain the contraindication information from a remote source database wherein the contraindication information comprise one or more indicators of patient allergy reactions, drug-to-drug

interactions or drug forulary changes...", which is not disclosed in Goldman et al.

IX. CONCLUSION

The Examiner has erred in the rejection of claims 79-83 under 35 U.S.C. § 102(e), at least because Goldman et al. does not clearly anticipate the claim element of "multiple record-independent facilities". The Examiner has erred in the rejection of claim 84 under 35 U.S.C. § 103(a), at least because Faden et al. does not clearly anticipate the claim element of "...access control [that] is maintained by reference to record-access specifications provided in a security profile in a pre-authorization file..." The Examiner has erred in the rejection of claim 84 under 35 U.S.C. § 103(a), at least because neither Ballantyne et al. nor Faden et al. teach or suggest the claim element of a "pre-authorization file". The Examiner has erred in the rejection of claim 70 under 35 U.S.C. § 103(a), at least because Fox does not teach or suggest the claim element of "...drug formulary information identifying at least one of multiple drugs as a patient's drug formulary preferences to enable selection by the prescriber of a benefit plan recommend drug..." The Examiner has erred in the rejection of claims 76-77 under 35 U.S.C. § 103(a), at least because Fox does not teach or suggest the claim element of a "...prescription creation system...comprising a drug contraindication review routine...access contraindication information regarding the prescribed drug and an alert regarding a relevant such contraindication."

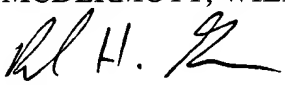
Based upon the arguments submitted *supra*, Appellants submits that the Examiner's rejections are not factually or legally viable. Appellants, therefore, respectfully solicit the Board of Patent Appeals and Interferences to reverse the Examiner's rejections.

To the extent necessary, a petition for an extension of time under 37 C.F.R. 1.136 is hereby

made. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 500417 and please credit any excess fees to such deposit account.

Respectfully submitted,

MCDERMOTT, WILL & EMERY



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